K051281 1/3

SEP - 8 2005

E.D.MEDICAL LTD.

SECTION 10 13/5/05

510(k) Summary

Please note 513g reference number CO40275

DATE OF APPLICATION:

APPLICANTS NAME: E.D.Medical LTD

ADDRESS: 32 Cranmore Avenue
Lisburn Rd
Belfast
BT 9 6 JH

CONTACT PERSON: Brian McNicholl

TELEPHONE: -353-87 239 2023

FAX: -353-1-663 6990

SIGNATURE:

MANUFACTURING SITE: UK and Pakistan

DEVICE DETAILS

TRADE NAME: Needlecatcher™

E.D. Medical Ltd ,32 Cranmore Avenue Lisburn rd, Belfast BT9 6 JH, N Ireland Ph 02890 666593 Fax 02890 285428 email brian.mcnicholl@ntlworld.com

COMMON NAME: Needlecatcher

CLASSIFICATION NAME: FORCEPS, HTD

10.1 LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED

Orthopaedic manual surgical instrument e.g. needleholder 888.4540
Forceps General and Plastic Surgery 878.4800

10.2 Description of the device

The Needle Catcher ™ is a stainless steel needle grasping instrument for use in suturing. The needle grasping element is combined with the traditional dissecting forceps to allow both tissue holding and needle grasping in the same instrument. The Needle Catcher ™ uses a piston and cylinder assembly to grasp and shield the suture needle during surgery to reduce the risk of needlestick injury and hold the needle safely during knot tying.

10.3 INTENDED USE OF THE DEVICE

For grasping suture needles during stitching and for transporting suture needles throughout the operating field.

10.4 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Needle Catcher ™ are similar to those of existing needle-grasping instruments such as the traditional needleholder used in suturing and the dissecting forceps. It uses two stainless steel surfaces to grasp steel surgical needles whilst allowing the tip of the needle to be shielded from patient and operator during use. The additional feature of needle-shielding allows the needle to be temporarily stored in a safe place while the surgeon performs other tasks such as knot tying or tissue dissection.

The needle is grasped between a piston which descends as the compression on the forceps arms are relaxed , and the inner surface of a metal cylinder which receives the needle.

10.5 SUBSTANTIAL EQUIVALENCE BASED ON PERFORMANCE DATA

Using the instrument on artificial skin and animal tissue with a variety of surgeons, nurse operators and medical students have indicated that it is safe and easy to use and that it achieves its goals of needle grasping and needle shielding.

10.6 CONCLUSIONS

The Needle Catcher ™ is a surgical needle grasping instrument specifically designed for use in suturing tissue to improve safety and ergonomics. Substantial equivalence is claimed to the tissue forceps and needleholder which are currently used in suturing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

Mr. Brian McNicholl
Managing Director
E.D. Medical LTD.
32 Cranmore Avenue Lisburn Road
Belfast BT9 6 JH
United Kingdom

Re: K051281
Trade/Device Name: The Needlecatcher™
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: HTD
Dated: July 7, 2005
Received: August 2, 2005

Dear Mr. McNicholl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051281

Indications for Use

510(k) Number (if known): K051281

Device Name: The Needlecatcher™

Indications for Use: The Needlecatcher is designed for grasping suture needles during suturing and holding them during transport throughout the operating theatre.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

...n Sign-Off) for MXM

...ision of General, Restorative,

...l Neurological Devices

...0(k) Number K051281